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Indus Biotech thrives on botanical breakthroughs

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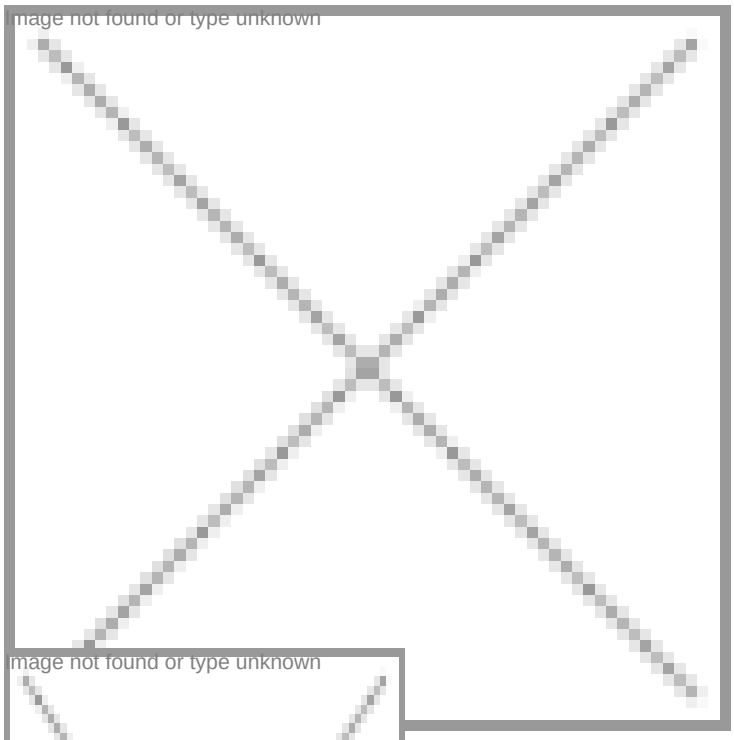

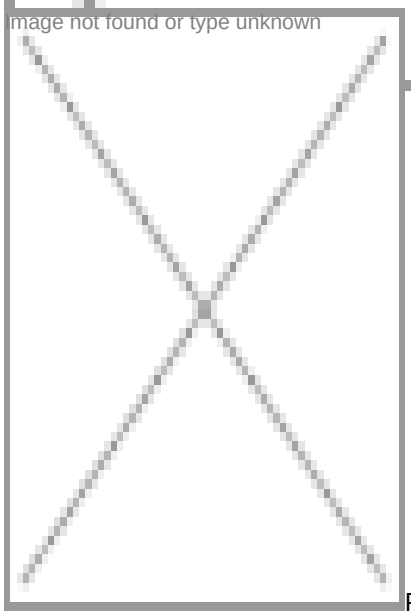

Pune-based Indus Biotech is a drug discovery company, which was founded in 1997. The company focuses on identifying and developing a new generation of efficacious and safe drugs for chronic lifestyle, autoimmune and degenerative diseases. It uses botanicals as a starting point that allows the company to significantly reduce drug development cost as well as time-to-market.

The company's inherent 'Engine' for the identification of novel molecules allows for a highly risk-mitigated approach to drug discovery. According to the company, the very core of its discovery process is based on a technology that facilitates the isolation and stabilization of individual molecules from botanicals with the potential pharmacological activity. An additional feature of this technology is its ability to maintain the structural integrity of isolated lead molecules and thereby preserving their functionality. The company has developed a pipeline of new chemical entities (NCEs), which are ready for commercial transaction and are backed by pre-clinical, clinical, toxicity and early 'proof-of-concept' studies.

Promising drug candidate

According to the founders of the company - Sunil Bhaskaran and Rajan Srinivasan â€“ other than the remedy for HIV/AIDS, the company is developing the botanical drug candidate as influenza A drug, which shows efficacy in various influenza A strains such as H1N1, H5N1 and H3N2.

The company has received an Investigational New Drug (IND) application approval from the US Food and Drug Administration (FDA) for this novel drug candidate, IND02. With this approval, Indus Biotech has become the first Indian drug discovery company to have obtained IND approval from FDA to start human clinical trials for this drug in the US. Furthermore, the company has also made an IND submission with the Drug Controller General of India (DCGI), the FDA equivalent of the country, and is awaiting clearance to start a large-scale study in India.

The company expects that after getting the approval, the clinical studies for H1N1 would take five to seven months, while for HIV it would take 18 to 24 months.

Highlighting the mechanism of action of IND02, Sunil Bhaskaran says, â€œIn simple terms, this drug converts HIV patients into what is called in scientific circles as 'HIV Controller' and people can lead normal lives with the disease, without the regular concerns like costly treatment or threat to their lives. "He further adds that one in 300 HIV patients is a 'Natural HIV Controller', who is able to block the progression of the disease by managing the virus and protecting the immune cells. IND02 is a drug candidate that acts as an 'enabler' that converts the HIV patient into an HIV controller.

According to the company, since it is a botanical drug, it has got huge advantages over the NCE drugs and biologicals. The company terms this drug as the 'third world answer for third world diseases'. This botanical drug would be affordable with less side-effects as compared to the anti-retroviral therapy (ART), the current first-line therapy for AIDS. The company estimates that the drug would cost only a fraction of ARTs.

Interestingly, the molecule has also shown new indications for the H1N1 strain as well as the H3N2 strain (avian flu). It has also shown to be effective on Tamiflu-resistant strains. â€œSince both are antiviral strains, we were curious to see whether the HIV molecule could also be a cure for the H1N1 strain and hence started with our studies in that area,â€? says Bhaskaran. Separate studies will be conducted for the H1N1 strain and 330 patients would be recruited for clinical trials. â€œWe have independently verified the studies in Japan and biosafety tests were conducted in the National Taiwan University Hospital in a P3P4 lab,â€? he adds.

Since the company is aiming at providing affordable drugs for neglected diseases to the third world countries, officials did not deny the prospect of approaching organizations like the Bill and Melinda Gates Foundation who in turn would provide the drugs at a subsidized price.

Future forward

In addition to the proprietary 'Engine' developed, Indus has two additional factors that allow its R&D to use a 'lower cost' and 'faster-to-market' approach. First, all potential drug candidates are isolated from food chain raw materials, thus minimizing issues related to toxicity on sustained use. The second factor is that being located in India, Indus Biotech uses the botanical-friendly regimen conforming to the country's regulatory requirement by conducting proof-of-concept studies at an early stage, much before regulatory studies, thus minimizing the risk of failure at a later stage.

Indus Biotech at present has seven NCEs in the pipeline with HIV/H1N1 (phase III) being the lead molecule. Others include diabetes (completed proof-of-concept studies and ready for phase III), rheumatoid arthritis (completed toxicology and proof-of-concept studies), Parkinson's (will move into human trials in another six months), Huntington's disease (at pre-clinical stage), kidney disease and depression. The company is also looking at other segments such as dengue and hepatitis 3.

"IND 02 converts an HIV patient into 'HIV Controller' and allows for a normal life with disease, free of concerns like costly treatment or threat to life"
- Sunil Bhaskaran, co-founder and MD, Indus Biotech, Pune

Ajeesh Anand in Bangalore